UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	Criminal No. 23cr10112
v.	)	Violation:
GREATER BOSTON BEHAVIORAL HEALTH LLC,	)	Count One: Receipt of Misbranded Drugs in Interstate Commerce (21 U.S.C. §§ 331(c), 333(a)(1))
Defendant.	)	Forfeiture Allegation: (18 U.S.C. § 982(a)(7), 28 U.S.C. § 2461(c), and 21 U.S.C. §§ 334 and 853(p))

INFORMATION

The United States Attorney charges that, at all times relevant to this information:

The Defendant

1. Greater Boston Behavioral Health LLC ("GBBH"), was a Massachusetts corporation providing medical services to patients, including treatment for chronic pain and migraines.

The Federal Food, Drug, and Cosmetic Act

2. The Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, regulated, among other things, the importation, manufacture, labeling, and distribution of drugs. The FDCA gave the United States Food and Drug Administration ("FDA") the authority to further regulate the importation, manufacture, labeling, and distribution of drugs to protect the health and safety of the American public.

3. Under the FDCA, the term "drug" was defined in relevant part as: (1) any article intended for use in the cure, mitigation, treatment, or prevention of disease in humans; or (2) any

article other than food intended to affect the structure or any function of the human body. 21 U.S.C. § 321(g)(1)(B) and (C).

4. The FDCA defined a "new drug" as, with limited exceptions, any drug that was not generally recognized as safe and effective among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs for use under the conditions prescribed, recommended or suggested in its labeling. See 21 U.S.C. § 321(p).

5. The FDCA defined "label" to include a display of written, printed, or graphic matter upon the immediate container of a drug. 21 U.S.C. § 321(k). The FDCA defined "labeling" to include all labels as well as other written, printed, or graphic matter upon a drug, or any of its containers or wrappers, or otherwise accompanying such drug. 21 U.S.C. § 321(m).

6. Unless there was in effect with the FDA a new drug application ("NDA") or an abbreviated new drug application ("ANDA"), a new drug was unapproved and could not lawfully enter into interstate commerce. *See* 21 U.S.C. §§ 355(a); 331(d).

7. A biological product that was a "new drug" was not required to have an approved NDA or ANDA if it was the subject of an FDA-approved Biologics License Application ("BLA"). *See* 42 U.S.C. § 262(j).

8. NDAs, ANDAs, and BLAs described how the product was manufactured, its components, and what was stated on the label and in the labeling. As part of the process, FDA must have approved the manufacturing process, and label set forth in the application. *See* 21 U.S.C. § 355(b)(1); 42 U.S.C. § 262(a). The approval process addressed, among other things, the elements of the distribution, such as the methods used in, and the facilities and controls used for, the product's manufacturing, processing, and packing; and the proposed label. *See* 21 U.S.C. § 355(b)(1)(A)-(F); 42 U.S.C. § 262(a)(2)(C); *see also* 21 C.F.R. § 601.2(a). The approval

process required, among other things, that a manufacturer provide the proposed text of the label for the product. *See* 21 C.F.R. §§ 314.50(c)(2)(i), (e)(ii), and (l)(1)(i), and 601.2(a). Approval granted to a particular manufacturer for a particular product to be imported into and distributed in the United States did not constitute approval of any drug or biological product—even one with the same chemical composition—with a label that differed in any way from the label in the FDA-approved application.

9. Some of the drugs regulated under the FDCA were "prescription drugs." "Prescription drugs" were those drugs which, because of their toxicity or other potential harmful effects, or the method of their use, or the collateral measures necessary to their use, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, or which were required by FDA to be administered under the professional supervision of a practitioner licensed by law to administer such drugs. 21 U.S.C. § 353(b)(1)(A) and (B).

10. The FDCA prohibited the receipt in interstate commerce of any drug that was misbranded and the delivery or proffered delivery of such drug for pay or otherwise, or the causing thereof. 21 U.S.C. § 331(c).

11. A drug was misbranded if it was a "prescription drug" and at any time prior to dispensing the label of the drug failed to bear the symbol "Rx only." 21 U.S.C. § 353(b)(4)(A).

12. A drug was also misbranded if its labeling did not bear adequate directions for its use. 21 U.S.C. § 352(f)(1). "Adequate directions for use" meant directions adequate for a "layman" to use the "drug safely and for the purpose for which it was intended." 21 C.F.R. § 201.5. Prescription drugs, by definition, were not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, or were required by FDA to be

administered under the professional supervision of a practitioner licensed by law to administer such drugs, and were therefore misbranded unless they qualified for an exemption.

13. A prescription drug was exempt from 21 U.S.C. § 352(f)(1) only if *all* of the listed conditions were met, including that: (1) the label bore the statement "Rx only"; (2) the label bore adequate information for its use, including any relevant hazards, side effects, and precautions under which medical practitioners could use the drug safely and was the labeling authorized by the FDA-approved new drug application. 21 C.F.R. §§ 201.100(b)(1), (c).

Botox® and Botox® Cosmetic

14. In 1989, FDA approved a BLA for Botox®, the brand name of a drug manufactured by Allergan, Inc.,[1] for the treatment of crossed eyes and spasm of the eyelids. Botox® was made up of the Botulinum Type A toxin, which was produced by the bacteria, Clostridium botulinum. The Type A toxin was a highly potent and potentially dangerous toxin, and could cause the disease botulism when present in human beings in a sufficient amount.

15. In 2002, FDA approved a supplement to Allergan's Botox BLA for the temporary improvement in the appearance of glabellar lines, commonly referred to as wrinkles. Under this FDA approval, Allergan's Type A toxin product was marketed and labeled for this supplemental usage as "Botox® Cosmetic." FDA's approvals for Botox® and Botox® Cosmetic limited them to use under the supervision of a licensed practitioner and required that their labels bear the symbol "Rx only."

16. On July 31, 2009, FDA approved several revisions to the labeling for Botox and Botox Cosmetic, including: (a) the addition of a "boxed warning" (sometimes referred to as a "black box warning") under 21 C.F.R. § 201.57(c)(1) cautioning that the effects of Botox and

[1] In May 2020, subsequent to the conduct identified herein, Allergan was acquired by AbbVie, Inc.

Botox Cosmetic may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism; and (b) a revision to the established name of the drug product (from "Botulinum toxin type A" to "OnabotulinumtoxinA") in order to emphasize that the different botulinum toxin products were not interchangeable because the units used to measure the products were different.

17. In 2010, the FDA approved Botox for treatment of chronic migraines in adults.

GBBH's Purchase and Use of Foreign Unapproved Botox

18. Beginning in 2012, GBBH sought out sources from which it could purchase Botox® ("Botox") that was manufactured, packaged, and labeled for sale in the United Kingdom and other foreign countries ("foreign Botox"). From in or about 2012 through in or about June 2019, GBBH purchased foreign Botox from a number of different sources.

19. The label of the foreign Botox purchased by GBBH differed from the FDA-approved label for Botox and Botox Cosmetic and lacked the designation "Rx Only" as required by the FDCA for prescription drugs. The label also typically did not include the FDA-required "black-box warning" concerning potential side-effects of Botox.

20. GBBH purchased foreign Botox at prices significantly below the price that Allergan and its authorized distributors charged for Botox and Botox Cosmetic that was manufactured and labeled for sale in the United States.

21. Doctors at GBBH used the foreign Botox to treat patients suffering from migraine headaches and did not disclose to these patients that they purchased the drug from foreign sources or that it was not labeled for distribution in the United States.

Count One
Receipt of Misbranded Drugs
(21 U.S.C. §§ 331(c); 333(a)(1))

22. The allegations set forth in Paragraphs 1 – 20 of this Information are incorporated and re-alleged as if set forth in full herein.

23. From in or around September 2012 through in or around June 2019, in the District of Massachusetts, defendant,

Greater Boston Behavioral Health LLC

received and caused the receipt of prescription drugs – specifically, foreign Botox – in interstate commerce that were misbranded within the meaning of: (i) 21 U.S.C. § 352(f)(1) in that their labeling failed to bear adequate directions for use, and (ii) 21 U.S.C. § 353(b)(4)(A) in that their labels failed to bear the symbol "Rx only," and delivered and proffered delivery of such misbranded drugs for pay and otherwise.

All in violation of Title 21, United States Code, Sections 331(c) and 333(a)(1).

FORFEITURE ALLEGATION
(18 U.S.C. § 982(a)(7), 28 U.S.C. § 2461(c), and 21 U.S.C. §§ 334 and 853(p))

24. Upon conviction of a violation of 21 U.S.C. §§ 331(c), 333(a)(l), as set forth in Count One,

Greater Boston Behavioral Health LLC

the defendant herein, shall forfeit to the United States any property, real or personal, that constitutes or is derived, directly or indirectly, from proceeds traceable to the commission of the offense and all right, title, and interest in any prescription drug that is misbranded when introduced into or while in interstate commerce or while held for sale after shipment in interstate commerce, or which may not, under the provisions of 21 U.S.C. § 331, be introduced into interstate commerce, pursuant to 18 U.S.C. § 982(a)(7), 21 U.S.C. § 334, and 28 U.S.C. § 2461(c). The property to be forfeited includes, but is not limited to, the following:

a. $1,929,464, to be entered in the form of a forfeiture money judgment.

25. If any of the property described above as being subject to forfeiture, as a result of any act or omission of the defendant:

a. cannot be located upon exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of this Court;

d. has been substantially diminished in value; or has been commingled with other property that cannot be divided without difficulty;

it is the intention of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 28, United States Code, Section 2461(c), to seek forfeiture of any other property of the defendant up to the value of the property described in paragraph 24.

All pursuant to 18 U.S.C. § 982(a)(7), 28 U.S.C § 2461(c), and 21 U.S.C. §§ 334 and 853(p).

Respectfully submitted,

RACHAEL S. ROLLINS
United States Attorney

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Date: April 14, 2023